

## **REMARKS**

Applicants have carefully reviewed the Office Action of September 5, 2007. Claims 22-36 are pending and have been rejected. Favorable reconsideration is respectfully requested.

### ***Claim Rejections under 35 U.S.C. § 102***

Claims 22, 25, 28, 30 and 35 were rejected under 35 U.S.C. § 102(b) as being anticipated by Walker (U.S. Patent No. 5,322,513). Applicants respectfully traverse the rejection for at least the reason that Walker does not teach or suggest all the claim elements.

Claim 22 recites in part “a seal member attached to the flanged end and covering the opening.” In formulating the rejection, the Examiner suggests that Walker discloses a flanged end with a seal covering the flanged end at column 7, lines 64-66 and Figure 1. Applicants respectfully disagree. The phrase “o-rings or other conventional sealing members” must be read in view of the teachings of Walker as a whole. When read in context, one of skill in the art would conclude that any seal suggested by Walker would not cover the opening of the access port. The seal disclosed by Walker is not used on the proximal end surface of a port nor does it seal an inflation lumen. As disclosed in Walker, the referenced seal is used to prevent inflation fluid from leaking past the interface between the cap 48 and the access port 51. In addition to this, Walker discloses at column 7 lines 67-68 through column 8 lines 1-4, “The inner collar 58 is preferably hollow to allow the pre-stripped portion of the body tubing to extend past the end of port 51 while cap 48 is sealed. This will allow easy access for the physician to pull on the end of the body tubing once the cap 48 is removed.” As is illustrated by Figures 1 and 2, the catheter extends beyond the end of port 51 into the cap 48 even when the cap is in place. Thus, one of skill in the art would understand that any seal chosen must be of an annular nature to maintain the end of the port 51 open to allow the passage of tubing therethrough. Dissimilarly, the seal in the presently claimed invention is intended to cover the entire port and remain in place until the physician is ready to remove the vacuum that has been applied. Applicants therefore submit that Walker does not disclose or suggest the desirability of a seal that is attached to a proximal end surface as recited in claim 22, nor does he suggest a seal that covers the opening.

For at least these reasons, Applicants respectfully submit that claim 22 is in condition for allowance. As claims 25, 28, and 30 depend from claim 22 and contain additional elements, Applicants submit that these claims are also believed to be in condition for allowance.

Similarly, claim 35 recites in part “a seal attached to the proximal end surface that seals the inflation lumen.” The Examiner suggests that Walker discloses a seal (column 7, lines 63-67 through column 8, lines 1-4) attached to the proximal end surface that seals the inflation lumen. Applicants respectfully disagree. As discussed above, the seal disclosed by Walker is not used on the proximal end surface of a port nor does it seal an inflation lumen. As disclosed in Walker, the referenced seal is used to prevent inflation fluid from leaking past the interface between the cap 48 and the access port 51. As mentioned above with reference to column 7 lines 67-68 through column 8 lines 1-4, Walker discloses, “The inner collar 58 is preferably hollow to allow the pre-stripped portion of the body tubing to extend past the end of port 51 while cap 48 is sealed. This will allow easy access for the physician to pull on the end of the body tubing once the cap 48 is removed.” As is illustrated by Figures 1 and 2, the catheter is able to extend beyond the end of port 51 into the cap 48 even when the cap is in place. As the catheter must be able to be passed through the end of the port 51 disclosed by Walker above, one of skill in the art would understand that any seal taught by Walker is not intended to cover the opening of the port 51. For at least these reasons, Applicants respectfully submit that claim 35 is in condition for allowance.

### ***Claim Rejections under 35 U.S.C. § 103***

Claims 23, 24, 27 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker (U.S. Patent No. 5,322,513). Applicants respectfully traverse the rejection for at least the reason that Walker does not teach or suggest all the claim elements.

First, each of these claims depends from claim 22, which Applicants submit is allowable and contains additional elements. For at least this reason, Applicants submit that these claims are in condition for allowance as well.

Additionally, Walker does not disclose the elements of these claims or suggest the desirability of modification to include these elements.

For example, claim 23 recites “wherein the seal has a cross-sectional area defined by a closed plane figure,” claim 24 recites “wherein the seal is generally planar” and claim 27 recites

“wherein the seal is self sealing.” The Examiner argues that such modifications would have been obvious “because Walker teaches ‘any conventional sealing members’ which is substantially broad enough to render obvious the overall claimed seal structure cited for claims 23, 24, 27 and 29.” Applicants respectfully disagree with this statement. In accordance with M.P.E.P. §2141.02(VI), the prior art must be considered in its entirety. Applicants maintain that in view of the teachings of Walker, the seal that Walker discloses at column 7 lines 64-66 must be annular in nature for the device to function as intended. Namely, with regard to the seal disclosed by Walker, the seal must be annular in nature, having a sufficient opening for the stripped catheter to pass through the seal into the interior of cap 48 as shown in Figure 1. Applicants again refer to column 7 lines 67-68 through column 8 lines 1-4 of Walker, which indicates the catheter may extend past the port through the central opening of the port even when the cap is sealed onto port 51. There has been no demonstration to indicate that a closed planar seal, a generally planar seal, or a self-sealing seal would adequately function under these circumstances.

Claim 29 recites “wherein the seal is releasably attached to the flanged region.” The Examiner argues that port 51 (see Fig. 2) of Walker’s invention contains the inflation lumen. However, as taught by Walker, port 51 is the port in which the catheter can be quickly removed and is not used as the inflation lumen. Applicants assert that Walker does not teach a seal releasably attached to a flanged region of the port 51.

For these reasons, it can be seen that Walker does not teach or suggest all the claim limitations, nor does Walker teach or suggest the desirability of such modifications.

Claims 26 and 31-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker (U.S. Patent No. 5,322,513) in view of Lopez at al. (U.S. Patent No. 5,344,414). Applicants respectfully traverse the rejection.

Claim 26 recites “wherein the seal is pierceable.” The Examiner suggests that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide pierceable seal the catheter of Walker for administration of fluid as taught by Lopez.” Applicants respectfully disagree. One of skill in the art would not have considered using the seal as taught by Walker for the administration of fluids. One of skill in the art would conclude that the “O-rings or other conventional sealing members” disclosed by Walker were designed to be annular in nature in order to allow a catheter or guidewire or other device to pass through as

designed. With regard to the sealing cap 48 (Fig. 2) of Walker's invention, it would also not benefit from being pierceable as the sole function of the port that this cap is sealing is for the removal of a catheter and not to inject any fluid. Since the application would not benefit from having pierceable seals, Applicants argue that it would not have been obvious to one of ordinary skill in the art at the time of the invention.

Claim 31 recites, in part:

a port disposed at the proximal end of the catheter shaft, the port having an opening defined therein that is in fluid communication with the inflation lumen; coupling a sealing device to the port, the sealing device including a vacuum source and a seal attachment means having a seal coupled thereto; applying the vacuum source of the sealing device to the inflation lumen until the air pressure therein is substantially less than atmospheric pressure; and disposing the seal across the opening in the port with the seal attachment means.

The Examiner suggests that "Walker teaches an inflation port where vacuum source can be applied (Figs. 2, 16), where air can be inherently taken out and put in." Applicants respectfully disagree. In accordance with M.P.E.P. §2112(IV), the Examiner must provide rationale or evidence tending to show inherency. The section states, "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Upon a careful reading of Walker and Lopez et al., neither Walker nor Lopez et al. reference a sealing device including a vacuum source or how to use one. It is reiterated that the sealing device taught by Walker is annular in nature and does not serve to fully seal a port. The seal taught by Lopez et al. is pierceable only for the purpose of delivering medication in a sterile manner. Therefore, at least because the cited prior art does not teach and disclose all the claimed elements of claim 31, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and that claim 31 as well as 32-34, which depend from claim 31, are in condition for allowance.

Claim 36 describes the method in which a balloon catheter is prepared in order to remove all air from the balloon and inflation lumen. The Examiner suggests "Walker teaches an inflation port where vacuum source can be applied (fig. 2, 16). Thus teaches a vacuum source can be applied through any port." Applicants respectfully disagree. As discussed above, upon a careful reading of Walker and Lopez et al., neither Walker nor Lopez et al. reference a sealing device including vacuum source or how to use one. Therefore, at least because the cited prior art

does not teach and disclose all the claimed elements of claim 36, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and that claim 36 is in condition for allowance.

**Conclusion**

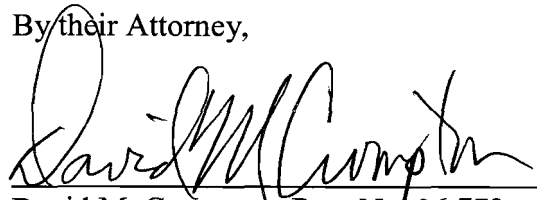
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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